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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/040,430	01/07/2002	Gerald R. Crabtree	APBI-P05-008	4837
28120	7590	03/02/2004	EXAMINER	
ROPES & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			MYERS, CARLA J	
			ART UNIT	PAPER NUMBER

1634

DATE MAILED: 03/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/040,430

Applicant(s)

CRABTREE ET AL.

Examiner

Carla Myers

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 22-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☒ Claim(s) 9, 10 and 19-21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to the amendment filed January 28, 2004. Applicants amendments and arguments have been fully considered but are not sufficient to overcome all grounds of rejection. This action is made final.

THE FOLLOWING ARE NEW GROUNDS OF OBJECTION / REJECTION NECESSITATED BY APPLICANTS AMENDMENTS TO THE CLAIMS

Claim Objections

2. Claims 9, 10 and 19-21 are objected to because of the following informalities:

Claims 9 (and dependent claims 10, 19-21) are objected to because "anNF-AT_n" should read "an NF-AT_n".

In claim 21, "encoded a nucleic acid" should read "encoded by a nucleic acid". It is noted that claim 21 is marked with the status of "(Original)". However, the claim was amended in the response of January 28, 2004 to delete the word "by".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-12 and 19-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9, 10 and 19-21 are indefinite over the recitation of "NF-AT" complex because it is not clear as to what constitutes this complex. The claims previously refers

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to a cell that comprises NF-AT_n and to a NF-AT_c containing complex. However, the claim does not clarify how NF-AT_n relates to the remainder of the claim and does not clarify the components of the NF-AT complex. This rejection may be overcome by amendment of claim 9, line 3, to recite "determining the level of NF-AT complex comprising NF-AT_c and NF-AT_n."

Similarly, claims 11 and 12 are indefinite over the recitation of "NF-AT" complex because the claims do not clearly define what constitutes this complex. This rejection may be overcome by amendment of claim 11, line 6, to recite "formation of an NF-AT complex comprising NF-AT_c and NF-AT_n."

THE FOLLOWING REJECTIONS ARE MAINTAINED

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No.

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6,352,830. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims of '830 are both inclusive of methods for identifying immunosuppressive or immunostimulatory compounds wherein the methods comprise assaying for a compounds ability to alter nuclear translocation of NF-ATc or assaying for compounds which alter the binding of NF-ATc to NF-AT_n or compounds which alter phosphorylation of NF-ATc.

5. Claims 1-21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-78 of U.S. Patent No. 6,150,099. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims of '099 are both inclusive of methods for identifying immunosuppressive or immunostimulatory compounds wherein the methods comprise assaying for a compounds ability to alter nuclear translocation of NF-ATc or assaying for compounds which alter the binding of NF-ATc to NF-AT_n or compounds which alter phosphorylation of NF-ATc. The method steps of the presently claimed invention are the same as those set forth in the claims of '099 and the claims of '099 generically screen for any compound that modulates the activity NF-AT which is inclusive of compounds that are immune regulating.

6. Claims 1-21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-90 of U.S. Patent No. 6,171,781. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims of '781 are both inclusive of methods for identifying immunosuppressive or immunostimulatory compounds wherein

the methods comprise assaying for a compounds ability to alter nuclear translocation of NF-ATc or assaying for compounds which alter the binding of NF-ATc to NF-ATn or compounds which alter phosphorylation of NF-ATc. The method steps of the presently claimed invention are the same as those set forth in the claims of '781 and the claims of '781 generically screen for any compound that modulates the activity NF-AT (i.e., compounds that modulate the translocation or phosphorylation or binding activity of NF-AT). The genus of compounds to be screened in the methods of '781 is inclusive of compounds that are immune regulating.

7. Response to Arguments:

In the response filed January 28, 2004, Applicants state that they will fill a terminal disclaimer upon the indication of allowable subject matter. Accordingly, the rejections are maintained for the reasons of record.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571)-272-0782.

Papers related to this application may be faxed to Group 1634 via the PTO Fax Center using the fax number (703)-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Carla Myers
February 25, 2004

Carla Myers 2/25/04
CARLA J. MYERS
PRIMARY EXAMINER